THANK YOU FOR JOINING ISMPP U TODAY!

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3:00 AM	7:30 AM	10:00 AM	11:00 AM	12:00 PM	10:00 PM **MONDAY JULY 13**	7:00 PM **MONDAY JULY 13**

MODERATOR

Kanaka Sridharan

- Head of Global Communications, Cell & Gene Therapies Unit, Novartis Pharmaceutical Corporation
- 20 years of experience as a medical publication professional
- Recently went on an international assignment to India
- Opportunity to coach and train our associates in India on the concepts of “Effective Medical Writing” and “Good Publication Practices”

Kalyan Pulipaka

- Team Lead, Immunology & Dermatology, Scientific services, Novartis Healthcare India
- 8 years of experience as a professional medical writer
- Coached several new associates in the Scientific services team, India

ISMPP ANNOUNCEMENTS

- Did you earn your ISMPP CMPP certification in 2010? Find out what you need to do to recertify (www.ismpp.org/recertification)
- Presentations from the 11th Annual Meeting are now available in the Archives (www.ismpp.org/annual-meeting-archive)
- Watch interviews with key presenters and stakeholders from the 11th Annual Meeting on our YouTube channel
- ISMPP is pleased to announce our first Asia Pacific meeting – registration is now open!

2015 ASIA PACIFIC MEETING OF ISMPP

REGISTRATION IS OPEN!

COLLABORATING FOR ETHICAL & EFFECTIVE MEDICAL PUBLICATIONS

Beijing, China • August 30, 2015

Tokyo, Japan • September 2, 2015

http://www.ismpp.org/asia-pacific-meetings

2015 ASIA PACIFIC MEETING OF ISMPP

COLLABORATING ON: ETHICAL & EFFECTIVE MEDICAL PUBLICATIONS

BEIJING AUGUST 30 ♦ TOKYO SEPTEMBER 2

PROGRAMME HIGHLIGHTS

- GPP3 (latest update, ***GPP3 for Authors*** checklist)
- **Four plenary sessions** exploring aspects of successful publication planning in AP
- Expert-moderated **roundtable sessions**
- Outstanding faculty from academia, industry, government, medical affairs, clinical research, medical journals

- **Keynote Speaker:** Professor Ana Marušić
  - President Elect, European Association of Science Editors (EASE), EQUATOR Network Steering Group member
  - Leadership experience at many influential organizations
  - Research on how industry sponsors work with investigators to ensure best authorship practice

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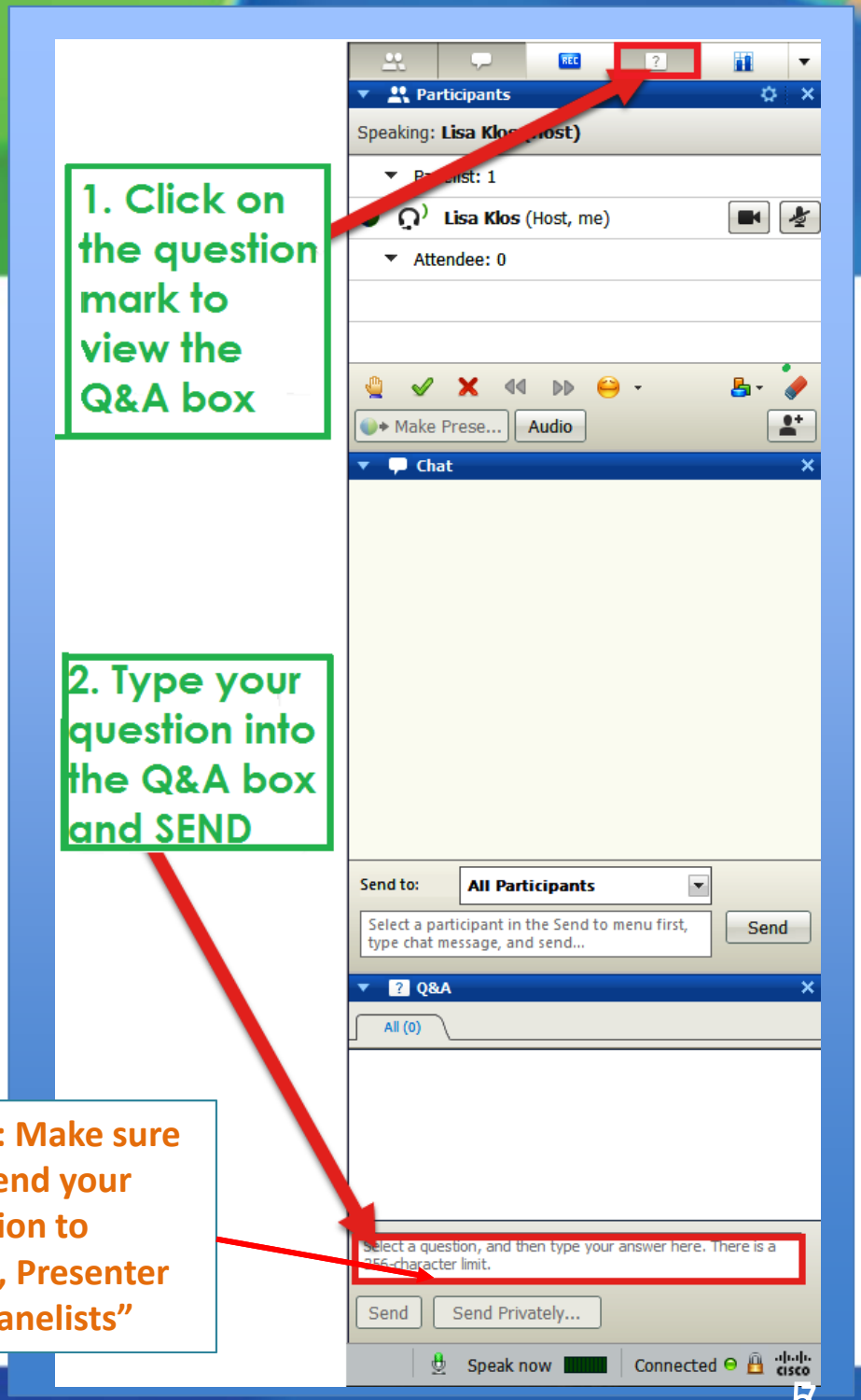
  - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "Hosts, Presenters and Panelists." Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions



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ISMPP WOULD LIKE TO THANK. . .

. . . the following Titanium and Platinum Corporate Sponsors for their ongoing support of the Society:

WAKING THE SLEEPING TIGER: OVERVIEW OF CLINICAL TRIALS AND PUBLICATION PRACTICES IN INDIA

Ajit Nair, PhD
Head, Global Scientific Services
Novartis Healthcare Pvt Ltd
Hyderabad, India

AUDIENCE POLLING QUESTION

Are you associated/or aware of your organization conducting global clinical trials in India

a) Yes
b) No
c) Not aware

AUDIENCE POLLING QUESTION

"Good Publication Practice" is a well known concept in India.

a) True
b) False

LEARNING OBJECTIVES

At the end of this session, attendees should be able to:

- Understand the current landscape of conduct of clinical trials in India
- Understand the importance and significance of increasing the awareness of good publication practice among medical publication professionals
- Identify the need for increasing the awareness of ISMPP and activities conducted by the organization in India

INTRODUCING THE SPEAKER

- Ajit Nair PhD, Head of Scientific services for Novartis Healthcare India, is responsible for the operational delivery of services related to medical communications, medical information, and clinical research services to global and the country pharma organizations within Novartis
- Ajit is responsible for leading a team of 180+ associates who support medical congress deliverables, publications, clinical data management, statistics, trial management, and regulatory medical writing activities

DISCLAIMER

The opinions presented here are those of the speaker and do not represent views of Novartis Healthcare Pvt Ltd or those of ISMPP

WAKING THE SLEEPING TIGER


CLINICAL TRIALS: DESTINATION INDIA

FIRST IMAGES OF INDIA

THE CULTURE

INDIA: THE CLINICAL TRIALS DESTINATION FOR THE WORLD

- "India can capture approximately $1 billion worth of global clinical research spending by 2010"

  ---McKinsey 2002

- It is a "sunrise industry"
  - "Government would provide required environment to help the country emerge as an attractive destination for outsourcing in drug discovery and clinical research"

    --Indian Finance Minister P. Chidambaram, Budget 2005-2006

REGULATIONS GOVERNING CLINICAL TRIALS IN INDIA

- Central Drugs Standard Control Organization (CDSCO)
  - Approval of new drugs, clinical trial applications, import registration
- Schedule Y of the D & C Rules – http://www.cdsco.in
  - Schedule Y (2005) pertains to new drugs for marketing in India
- India GCP guidelines
  - http://www.cdsco.nic.in/html/GCP1.html
- ICMR guidelines for Ethics in Human Experimentation
  - http://www.icmr.nic.in/human_ethics.htm

CONDUCTING CLINICAL TRIALS IN INDIA

Investigators

- Large pool of English-speaking physicians
- Highly trained specialists in different therapy segments with many trained in the UK/US
- Treatment methodology similar to the Western world
- Investigators/sites compliant to ICH/GCP guidelines

Patient population

- Large, diverse, patient pool, many treatment-naïve
- Genetic diversity
- Prevalence of acute and chronic diseases
- Increasing prevalence of life style diseases

CONDUCTING CLINICAL TRIALS IN INDIA: THE ADVANTAGES

Infrastructure

- >380 Medical Colleges, 600-650K physicians
- 15,622 hospitals, more than 75% in urban area
- >14,000 diagnostic labs
- World class medical/lab facilities at secondary/ tertiary care centers. including the latest diagnostic and therapeutic medical equipment
- Skilled computer savvy biomedical work force
- IT infrastructure to run electronic data capture (EDC) from studies

http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/1_India_ClinicalTrialsNewHorizon.pdf

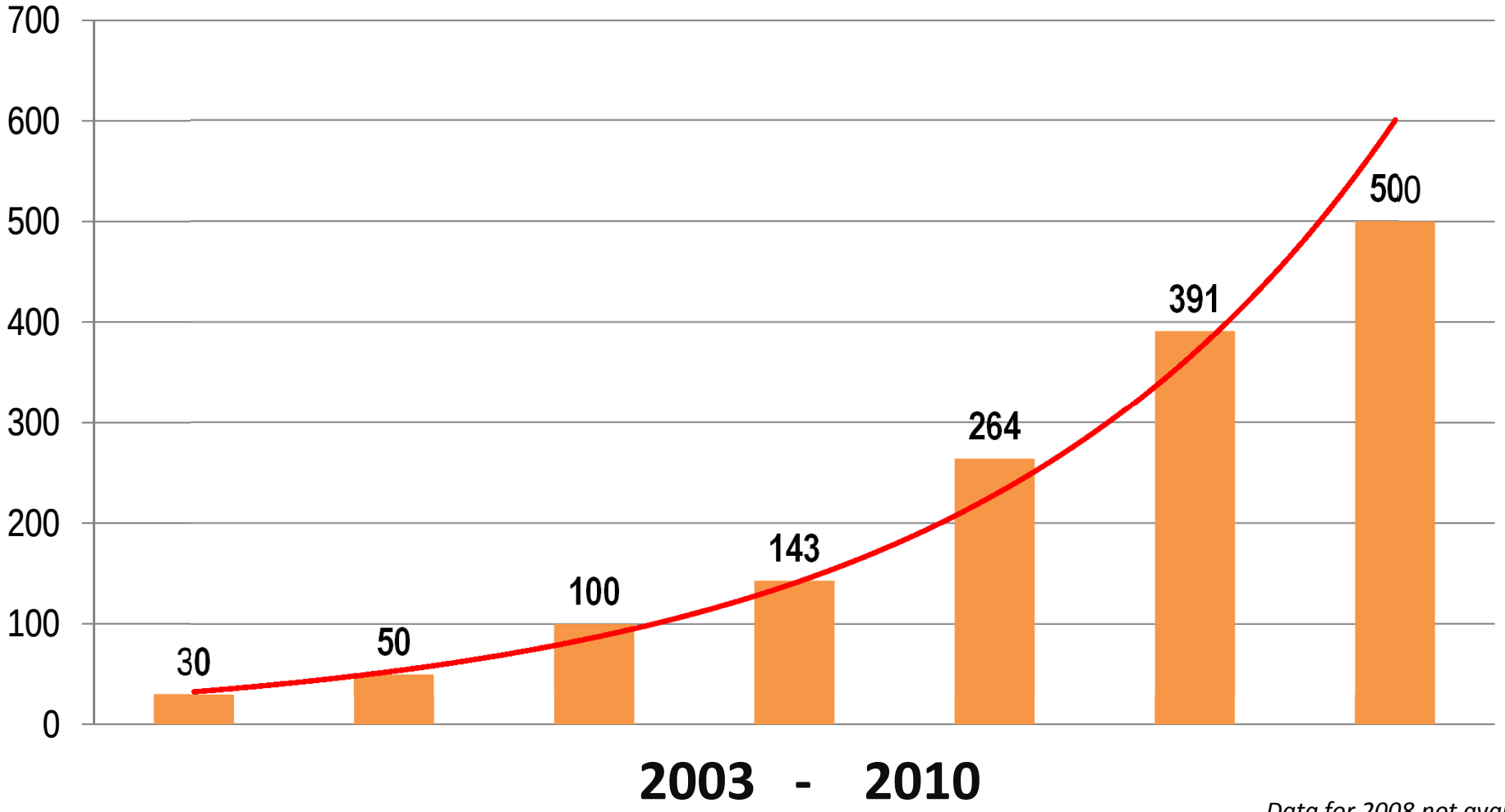
CONDUCTING CLINICAL TRIALS IN INDIA: THE ADVANTAGES

Regulatory & Cost

- Clinical trial approval process not complicated
- Approvals for conducting trials and importing drugs from one central body
- Average timelines of 3-4 months for approval
- Almost 50% savings on overall costs from a site and clinical research professionals perspective

http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/1_India_ClinicalTrialsNewHorizon.pdf

NUMBER OF CLINICAL TRIALS CONDUCTED IN INDIA



Data for 2008 not availble

Source: Clinical trials New Horizon. Dr. Surinder Singh DCGI
http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/1_India_ClinicalTrialsNewHorizon.pdf

THE BUBBLE BURSTS!

NDTV

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Drug trials in India 'causing havoc to human life': Supreme Court

India | Agence France Presse | Updated: January 03, 2013 13:53 IST

NEW DELHI: Supreme Court said on Thursday that unregulated clinical trials of new drugs were causing "havoc" in the country as it ordered the health ministry to monitor any new applications for tests.

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NEWS » NATIONAL

NEW DELHI, January 3, 2013

Updated: January 3, 2013 16:17 IST

Illegal clinical trials creating "havoc": Supreme Court

PTI

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Clinical Trials

+ Font Resize -

Swasthya Adhikar Manch asks Health Min for position paper on how trials benefiting Indians

Joseph Alexander, New Delhi

Wednesday, October 23, 2013, 08:00 Hrs [IST]

Swasthya Adhikar Manch, the NGO fighting against the irregularities in clinical trials, has asked the government to come out with a position paper on how the new chemical entities (NCEs) and new molecule entities (NMEs) are cleared for trials in the country.

The NGO spokesman said they made the demand for the position paper in the affidavit filed in the Supreme Court on Monday, during the hearing of its petition filed in February 2012 alleging that the NCEs and NMEs were benefiting the multinationals at the cost of human lives in India.

The petitioner, which pushed the government to the wall on clinical trials issue and prompted Supreme Court to take a harsh view about the alleged irregularities in trials, also wanted the Union Health Ministry to provide details of 162 approved clinical trials-- name of molecule, indication, name of sponsor, protocol, sites, number of subjects, name of investigators and minutes of New Drug Advisory Committee, apex and technical committee meetings.

"When the Court enquired on how many out of 162 trials had molecules patented outside country and benefited MNCs instead of development of new drug, Additional Solicitor General representing the government could not give the answer," the NGO said.

The Supreme Court has ordered the re-examining of 157 trials approved by the Drugs Controller General of India (DCGI) during 2012 while pointing out that the trials should benefit the people and not the MNCs. The Bench headed by R M Lodha also directed the government to put in place fool-proof mechanism including audio-video recording before allowing the commencement of five trials, approved by the DCGI this year.

FINANCIAL EXPRESS

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Sensex : 21108.25 0.06 BPCL : 835.65 0.22 Cairn India : 179.75 0.59 Cipla : 606.65 -0.07 Coal India : 393.65

MARKET STATS As on 19/06/2015 SENSEX 27316.17 200.34 (0.74%) NIFTY 8224.95 50.35 (0.62%) GOLD (MCX) 26884.00 40.00 (0.15%)

HOME FRONTPAGE

India losing out on clinical trial biz pie

Soma Das | New Delhi | Updated: Jul 09 2012, 03:13 IST

THE CHAIN OF EVENTS

2009
- PATH & ICMR initiated Phase IV study of HPV vaccine in 2 states

2010
- Trial suspended as human rights & women group alleged unethical practices

2012
- NGO (Swasthya Adhikar Manch) files PIL seeking justice for patients in clinical trials

2013
- Supreme Court suspends all trials in the country

PATH, Program for Appropriate Technology in Health; NGO, Non-government Organization; PIL, Public Interest Litigation, HPV, Human papillomavirus; ICMR, Indian Council of Medical Research

THE IMPACT

2011

- Twelve NDAC (New Drug Advisory Committee) constituted for approval of clinical trials.

2013

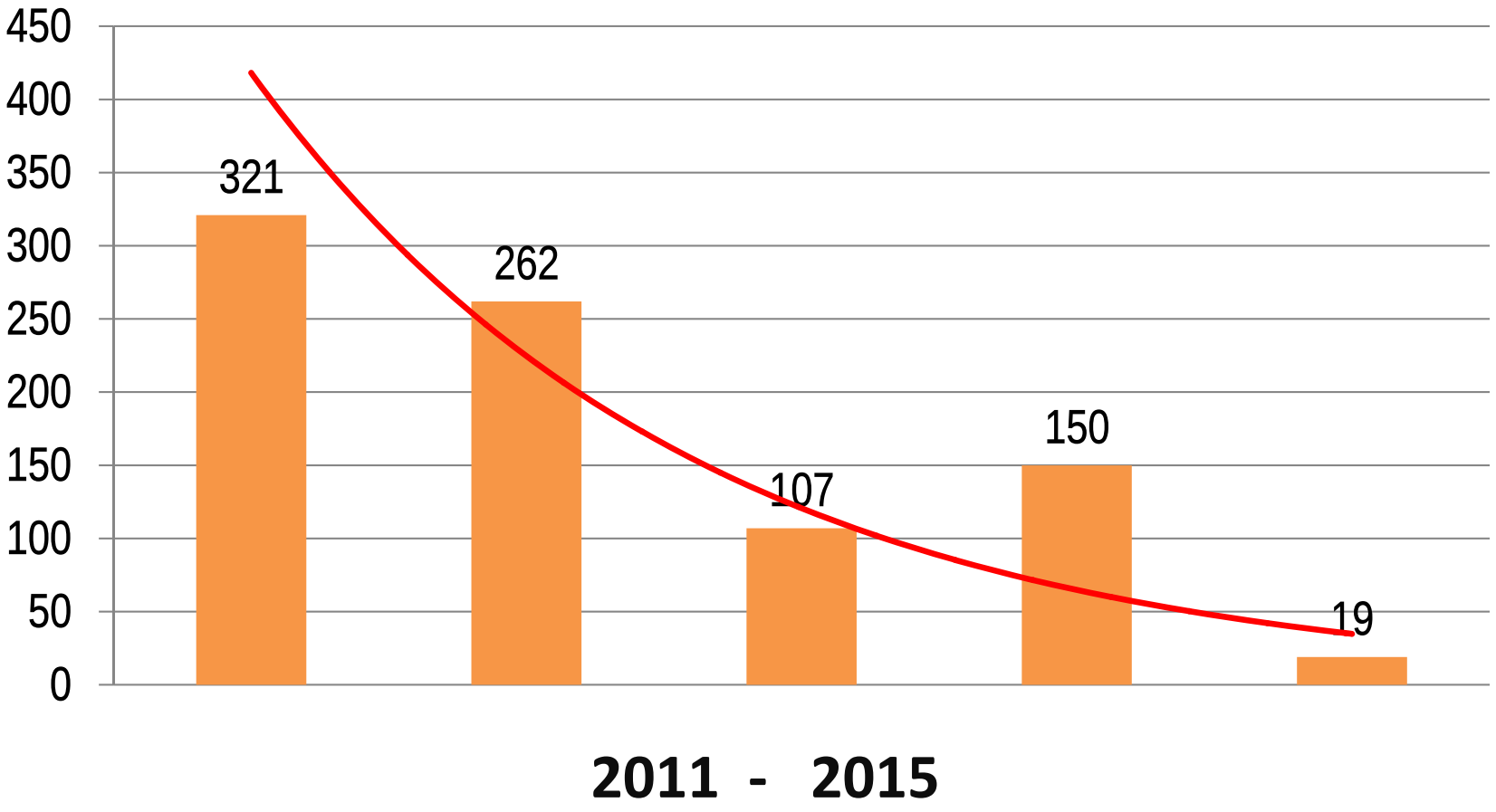
- Amendments of D&C rules to cover SAEs and patient compensation
- New policy guidelines implemented for approvals of new drugs & trials

NDAC, new drug advisory committee D&C Act, drug and cosmetic act; SAE, serious adverse event;

THE IMPACT

- Compensation clauses for trial participants
- Multiple committees to get approvals thereby extending the timelines by an average of 6-9 months
- Audio/video recording of informed consent process
- Restriction on number of trials per investigator (maximum 3) and at least two government hospitals to be included
- Registration of “Ethics Committees” with health authority

THE IMPACT



Data for 2015 upto April

Source: CDSCO website reports

Publications: Current Scenario in India

CLINICAL PUBLICATIONS & REGULATIONS

- Clinical Trials Registry of India
  www.ctri.nic.in
- Drugs & Cosmetic Rules
  http://www.cdsco.in
- Indian GCP
  http://www.cdsco.nic.in/html/GCP1.html
- ICMR guidelines for Ethics in Human Experimentation
  http://www.icmr.nic.in/human_ethics.htm

CLINICAL TRIALS REGISTRY - INDIA
NATIONAL INSTITUTE OF MEDICAL STATISTICS
(INDIAN COUNCIL OF MEDICAL RESEARCH)

D&C Act, drug and cosmetic act, GCP, good clinical practice, ICMR, Indian council of medical research

CLINICAL TRIAL REGISTRY OF INDIA (CTRI)

Vision of CTRI

- Improve transparency & accountability
- Improve internal validity of trials
- Conform to acceptable ethical standards
- Reporting of all relevant results of registered trials

GCP & ICMR

- Research results should be brought forth in public domain via publications, keeping patient confidentiality in mind
- Principle of making results available in public domain protecting patient confidentiality
- Defines the requirement that an IRB/EC submission should have a defined publication plan for the study results
- Defines authorship obligations and also that negative or positive results should be published
- Protocol for submission should have a publication policy defined

ICMJE: International committee of medical journal editors

USE OF PUBLICATIONS IN THE INDIAN PHARMA INDUSTRY

- Medical departments primarily responsible for publications in pharma companies
- Promotional materials where claims are made need to have references to publications
- Concept of 'Medical Science Liaison' is relatively new in India, hence discussions around published data by medical (sales) representative is not common
- Generic companies use innovator published & bioequivalence data to talk about their brands
- Local studies conducted mainly to award authorship and not necessarily a part of strategic publication plan or to help in the discussion with health authority

CURRENT UNDERSTANDING OF PUBLICATION PRACTICE IN INDIA

Background: Manuscript authors of scientific journals are expected to report if their studies were conducted according to international and national ethical guidelines and inform readers regarding ethics approval and informed consent obtained from participants and/or their legally acceptable representative/s. In the present study we assessed the reporting practices of ethics approval and informed consent (assent in case of pediatric studies) in four Indian journals. **Materials and Methods:** Original research articles published over a period of 4 years (2009-2012) in four major national clinical journals, viz. Journal of Association of Physicians of India (JAPI), Indian Journal of Surgery (IJS), Journal of Obstetrics and Gynecology of India (JOGI), and Indian Journal of Orthopedics (IJO) were reviewed with regard to documentation of ethics approval and written informed consent and assent in case of pediatric participants. **Results:** We reviewed 673 research articles and found that, overall ethical approval was mentioned in 163 (24.2%) and informed consent or assent was mentioned in 179 (26.5%) articles in all four journals. Individually we found, in JAPI of the 174 manuscripts reviewed, 74 (42.5%) reported having obtained approval from the ethics committee and 68 (39.1%) reported taking written informed consent from participants. In IJS of 123 manuscripts, 18 (14.6%) reported ethics committee approval and 20 (16.2%) reported informed consent from participants. In JOGI of 152 manuscripts, 21 (13.8%) reported ethics committee approval while 49 (32.2%) reported informed consent from participants. In IJO, of 224 manuscripts, 50 (22.3%) reported ethics committee approval and 42 (18.7%) reported obtaining informed consent. **Conclusion:** Majority of the publications did not provide information regarding compliance to ethical guidelines in spite of the availability of various guidelines. Thus, there is a need for awareness and training on bioethics for authors, reviewers, and editors of biomedical journals.

Abstract

This study was planned as an exploratory study to determine the extent of occurrence of misconduct in publication (gift-authorship, ghost-authorship, falsification of data, fabrication of data, plagiarism, and duplication) amongst biomedical researchers. It was a questionnaire-based study, conducted at 9 institutions; 6 medical colleges (4 government-run and 2 private), 1 non-teaching government hospital, and 2 corporate hospitals, located in northern, central and southern India. The study was conducted between August 2012 and March 2013. 155 senior residents (<3 years after post-graduation) and young faculty members (<10 years after post-graduation) with at least five previous publications were administered a structured questionnaire, in which no identifying information was collected. In addition to personal characteristics, the information collected included their knowledge of publication ethics, their opinions about the prevalence of these practices among their colleagues, and details of any first-hand information on publication misconduct. 155 responses were included for analysis. 141 (91%) respondents agreed that they had some knowledge of publication ethics; but only 29% believed it was adequate. The most commonly observed misconduct was offering gift authorship, reported by 101 (65%); followed by alteration of data reported by 88 (56%). Plagiarism was observed by 83 respondents (53%); while 52 (33.5%) respondents had observed a colleague's name being omitted from a paper to which she/he had significantly contributed. A majority of respondents in the present study reported witnessing publication misconduct, thereby revealing the common occurrence of this problem among

Dhingra D, Mishra D. Indian J Med Ethics. 2014;11(2):104-7.

Belhekar MN, Bhalerao SS, Munshi ES. Perspectives in Clinical Research. 2014:5:129-33

NEED FOR INCREASING AWARENESS ON GOOD PUBLICATION PRACTICES IN INDIA

- Need for Indian journal editors to enforce ICMJE/CONSORT requirements
  - Some journals have made it mandatory to have trial registered on CTRI before manuscript is submitted for review
- Need for significant improvement in adhering to ICMJE guidelines
- Need to increase awareness on good publication practices (GPP2/3) in India
- Increase awareness and education among academic and practicing physicians on “ghost writing” practices

1. www.indianjpsychiatry.org/cpg/cpg2009/article4.pdf

INCREASING AWARENESS OF GOOD PUBLICATION PRACTICES IN INDIA: GAZING INTO THE CRYSTAL BALL

- Medical publication and planning activities still at infancy stage in India
- Increasing awareness of "Good publication practices (GPP2/3)" is critical for all medical researchers and physicians
  - Inclusion of GPP in medical curriculum
  - Journal editors & reviewers can aid in increasing awareness
  - Medical journals to be more stringent in reviewing and scrutinizing data submitted for publication
  - Global pharmaceutical industry can also help in increasing awareness

MEDICAL PUBLICATION PROFESSION: A CAREER OPTION IN INDIA

- Talented qualified pool available
- Medical publication profession is still not the preferred option for talent entering the industry
- As more CMPP professionals get trained in India, a general increase in the awareness, education and application of international practices/guidelines (ICMJE/GPP2/3) can be driven by these individuals
- ISMPP can help significantly if there can be an India chapter

GPP: good publication practice; ISMPP: international society for medical publication professionals

Acknowledgements

Thanks to Kalyan Pulipaka for research assistance and providing editorial support for this presentations

So when are you coming to India?

Thank you.

QUESTIONS . . .

- To ask a question, please type your query into the Q&A box
- To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, ALL audience members will be able to see your submitted question
- Due to the nature of this particular ISMPP U topic and the fact that it is an overview of many individual presentations, we may not be able to answer all questions. We are happy to follow up with specific faculty after the ISMPP U if needed.

UPCOMING ISMPP U'S

- July 22, 2015
  - Topic: Real World Evidence
  - Presenters:
    - Richard White, MA, PhD, Commercial Director, Oxford PharmaGenesis Ltd
    - Timothy Koder, PhD, Account Director, Oxford PharmaGenesis Ltd

- September 23, 2015
  - Topic: Predatory Journals
  - Presenter:
    - Jeffrey Beall, MA, MSLS, Scholarly Initiatives Librarian/ Associate Professor, Auraria Library, University of Colorado, Denver, Colorado

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- We hope you enjoyed today's presentation. Please take a few moments to **complete the survey that will appear on your screen** immediately after the presentation. We depend on your valuable feedback and take it into account as we develop future educational offerings